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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,452	12/28/2001	Howard Milne Chandler	13521-002001	4341
7590	01/26/2005			EXAMINER
Janis K. Fraser Phd J D Fish & Richardson P C 225 Franklin Street Boston, MA 02110-2804				CROSS, LATOYA I
			ART UNIT	PAPER NUMBER
				1743

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/936,452	CHANDLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 05 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-6 and 8-34 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 8-34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on November 5, 2004.

Claims 1-6, 8-34 are pending.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 9-13 and 15-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,939,252 to Lennon et al.

Lennon et al teach assay devices having multiple panels/modules hingedly attached to each other. With respect to claim 1, Lennon et al teach a device (10) is shown having a housing with a first panel (12) attached to second panel (14). The first panel (12) has an opening (aperture) forming a first receptacle (20) for a sample collection device. A second receptacle (22) for a test strip is formed in the first panel. When closed, the second panel (14) shields the sample collection device. Also, when the first and second panels are closed, the fluid from the sample collection device is applied to the test strip for detection or determination of the presence of an analyte, as recited in claim 3 (col. 11, lines 12-30). Lennon et al teach that the test strip can be inserted after closing the second panel on top of the first panel (col. 11, lines 50-54). At col. 11, lines 31-32, Lennon et al teach using a swab as the sample collection device, as recited in claims 4-6, 19 and 20. The test strip used in the device is a chromatographic

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medium for immunoassays, as recited in claims 9 and 18 (col. 11, lines 33-34; col. 12, lines 12-13). A different embodiment of Lennon et al (figure 8) teach a housing having an opening (108) for the sample collection device, an opening (114) for the test strip (116), and a window (112), wherein when panels (102, 104 and 110) are folded onto each other the sample fluid is applied to the test strip. At col. 21, lines 47-52, the reference teaches that two or more test strips can be provided, as recited in claims 10-12. With respect to the method recited in claims 16 and 17, Lennon et al teach collecting a sample on a sample collection device, such as a swab. Next, the sample carrying device is inserted into the receptacle (20), followed by inserting the test strip into test strip receptacle (22) and closure of the two panels (12, 14). Alternatively, the two panels can be closed and the test strip inserted after the panels are closed. Also, reagents may be added to the sample collection device. See col. 13, lines 9-27 and lines 42-43. With respect to claim 18, Lennon et al teach that the device may be used to analyze blood or fecal matter, presumably from a patient (col. 23, line 64 – col. 24, line 15). Further, with respect to claims 21 and 22, Lennon et al teach that the use of a separate test strip assembly allows the sample portion of the device to be treated, such as by heating, prior to being exposed to the test strip (col. 24, lines 40-51). Such allows the sample to be collected, treated and later analyzed. With respect to claims 23 and 24, the reference teaches applying extraction reagents to the sample collection device (col. 21, lines 20-25). The extraction reagent will solubilize any portions of the sample that may have dried since being collected. With respect to claims 25 and 27-29, the housing consists of at least two panels, which may serve as covers, that when closed create an opening for the test strip to be inserted. For example, in the embodiment shown in figures 2 and 3, when the housing is folder, the swab would be sandwiched between the panel (52, 106) of the housing and the panel (56, 104) containing the test strip. With respect to kit claims 30-34,

Lennon et al teach kits comprising the device with receptacles (20, 22) and cover panels, at least one test strip and swabs (col. 21, lines 10-52).

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennon et al in view of US patent 6,165,416 to Chandler.

With respect to claims 8 and 14, Lennon et al fails to teach a guaiac-based test strip. Chandler '416 teaches that both immunochromatographic test strips and guaiac test strips are suitable for detecting analytes in bodily samples, especially the detection of occult blood in fecal samples. At col. 11, lines 3-13, the reference teaches that guaiac test strips are the most widespread technology for occult blood testing and the tests are rapid, inexpensive and easy to use. It would have been obvious to one of ordinary skill in the art to use guaiac test strips disclosed by Chandler '416 because of their ability to detect analytes simply and fast.

***Response to Arguments***

5. Applicant's arguments filed on November 5, 2004 have been fully considered but they are not persuasive.

With respect to the anticipation rejection over Lennon et al, Applicants argue that Lennon et al fail to teach a first aperture communicating with the internal recess and an additional aperture, separate from the first aperture, communicating with the internal recess.

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In response, the Examiner would like to point out that Lennon et al teach that the first panel (16) is mounted onto second panel (18), creating a space in between the two panels. This space creates an internal recess and holds a chromatographic test strip. Lennon et al further teaches that there exists a first opening (20) for the sample collection device and a second opening (22) for a test strip. Lennon et al explicitly teaches, "the test strip is inserted into the second receptacle (22)" See col. 11, lines 15-47. Referring to figure 1, the first opening (20) is in communication with the internal recess holding the test strip. Also, the opening (22) is in communication with the internal recess.

Thus, Lennon et al do teach two separate apertures being in contact with the internal recess. And the reference further teaches that the second aperture allows for insertion of a test strip.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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